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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,407	10/30/2003	Toyonobu Tanaka	03-211	7232

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EXAMINER	
MORILLO, JANELL COMBS	
ART UNIT	PAPER NUMBER
1742	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/697,407	TANAKA ET AL.	
	Examiner	Art Unit	
	Janelle Combs-Morillo	1742	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-15* is/are pending in the application.

4a) Of the above claim(s) *12-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 3-6, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuo (US 2002/0033717) in view of "ASM Handbook Vol. 2" p 599.

Matsuo teaches a biocompatible titanium alloy of the formula $Ti_{100-x-y}\ M1_xM2_y$, wherein M1 selected from a group including Nb; M2 selected from a group including Mo; x+y is 20-80at% [0020], y=1-5at%, x=20-50at% [0021], which falls within the presently claimed composition ranges (cl. 1, 3-5). Furthermore, "ASM Handbook Vol. 2" teaches that Mo is added to titanium alloys for the known purpose of (as a beta stabilizer) promoting hardenability and short-time elevated temperature strength (p 599, 3rd column), and therefore teaches motivation to select Mo from the markush type group of Matsuo.

Though Matsuo does not specify said alloy is superelastic, because the composition taught by Matsuo falls within the presently claimed alloying ranges, substantially the same degree of superelasticity is expected for Matsuo as in the instant alloy. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of

the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. The prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See also Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), see MPEP 2112.01.

Overlapping ranges have been held to be a prima facie case of obviousness, see MPEP § 2144.05. It would have been obvious to one of ordinary skill in the art to select any portion of the range, including the claimed range, from the broader range disclosed in the prior art, because the prior art finds that said composition in the entire disclosed range has a suitable utility. Additionally, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages," In re Peterson, 65 USPQ2d at 1379 (CAFC 2003). Because Matsuo teaches an overlapping alloy composition, and "ASM Handbook Vol. 2" teaches motivation to select Mo from the markush type group of Matsuo, it is held that Matsuo combined with "ASM Handbook Vol. 2" has created a prima facie case of obviousness of the presently claimed invention.

Concerning claim 6, Matsuo teaches said biocompatible Ti alloy can be used for medical instruments [0004]. Though Matsuo does not mention the particular presently claimed medical products, the phrase "the alloy is for use in..." as claimed is held to define merely an intended use for the alloy composition. Because the prior art teaches an alloy suitable for medical

instruments, said alloy appears to be capable of performing said intended use as recited. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997), MPEP 2111.02.

Concerning claim 10, Matsuo teaches said biocompatible Ti alloy can be used for spectacle frames [0004].

3. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuo (US 2002/0033717) and "ASM Handbook Vol. 2" p 599 in view of Hanada (US 6,786,984).

Matsuo does not teach forming said Ti alloy into guide wires, stents. However, Hanada teaches that biocompatible Ti alloys can be used for stents and guide wires (column 4 lines 10, 13). It would have been obvious to one of ordinary skill in the art to form the alloy taught by Matsuo into a stent or guide wire, because Matsuo teaches said alloy has good biocompatibility and can be formed into a variety of medical instruments.

4. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuo or Hanada and "ASM Handbook Vol. 2" p 599 in view of Gotanda (US 4,987,314).

Neither Matsuo nor Hanada teach forming said Ti alloy into actuator of an endoscope. However, Gotanda teaches that biocompatible Ti alloys (column 4 line 66) can be used for actuators of an endoscope (abstract, column 3 lines 59-60). It would have been obvious to one of ordinary skill in the art to form the alloy taught by Matsuo or Hanada into a actuator of an endoscope, because Matsuo teaches said alloy has good biocompatibility and can be formed into a variety of medical instruments (Matsuo at [0004]), or because Hanada teaches said alloy has high biocompatibility (column 1 lines 42-47).

5. Claims 1, 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanada (US 6,786,984) and "ASM Handbook Vol. 2" p 599.

Hanada teaches a biocompatible titanium alloy comprising (in at%): 3-6at% Sn, 8-20at% Nb, balance titanium (column 10, claims 1 and 3). Hanada teaches said alloy is superelastic and exhibits shape memory effect (column 9 lines 30-33). Though Hanada does not teach the addition of Mo, Al, Ge, Ga, or In; Hanada does teach that Mo has moderate biocompatibility (Fig. 1). Furthermore, "ASM Handbook Vol. 2" teaches that Mo is added to titanium alloys for the known purpose of (as a beta stabilizer) promoting hardenability and short-time elevated temperature strength (p 599, 3rd column). Additionally, "ASM Handbook Vol. 2" teaches Ge and Ga are added to titanium alloys for the known purpose of stabilizing the alpha crystal structure. Changes in concentration or temperature will generally not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical, i.e. they produce a new and unexpected result. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382. A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). In the instant case, the addition of Ge, Ga, and Mo are held to be result effective variables, wherein the expected result is stabilization of the crystal structure and/or promoting hardenability and elevated temperature strength. Therefore, it would have been obvious to one of

ordinary skill in the art to add Mo, Ge, or Ga as taught by "ASM Handbook Vol. 2" to the titanium alloy taught by Hanada, for the above mentioned recognized result.

Therefore, it is held that the alloy taught by the combination of Hanada and "ASM Handbook Vol. 2" overlaps the ranges of instant claims 1, 3-5. Overlapping ranges have been held to be a prima facie case of obviousness, see MPEP § 2144.05. It would have been obvious to one of ordinary skill in the art to select any portion of the range, including the claimed range, from the broader range disclosed in the prior art, because the prior art finds that said composition in the entire disclosed range has a suitable utility.

Concerning claims 6-9, Hanada teaches that said biocompatible Ti alloys can be used for stents, guide wires (column 4 lines 10, 13), orthodontic wire (column 4 lines 29-30).

Concerning claim 10, because Hanada teaches said alloy is formable into drawn wires, etc. (column 4 lines 43-52) it would have been obvious to one of ordinary skill in the art to draw said alloy into a frame for eyeglasses or a nose pad arm.

Response to Amendment/Arguments

6. In the response filed on December 12, 2006 applicant amended claims 1, 3-11. Claims 1, 3-15 are pending, claims 12-15 are withdrawn from consideration. The examiner agrees that no new matter has been added.

7. The examiner agrees that the 102(b) rejection in view of Matsuo has been overcome in view of the addition of cl. 2 into cl. 1 and removal of Al from the markush type group. However, the instant claims are rejected under 103(a) in view of Matsuo as set forth above.

8. Applicant's argument that the present invention is allowable over the prior art of record because the descriptions of Ga, Ge, and Mo of "ASM Handbook Vol. 2" teach only general

features of said elements, and do not teach alloys such as Ti-Nb-Ge alloy D-6, Ti-Nb-Fe alloy D-1, Ti-Nb-Mo alloy B-6 (that is, alloys with 5-40at% Nb and at least one selected from the group consisting of: 3-10at% Ga (Table 5), 5-15at% In (Table 6), 5-10at% Mo (Table 2), and 3-10at% Ge (Table 4)), would have a shape recovery effect, has not fully been found persuasive.

Applicant has not shown that the presently claimed ranges of Ga, In, Mo, Ge (wherein the instant claims do not recited a minimum) are effective to produce an unexpected shape memory effect. Additionally/alternatively, the examiner points out the instant claims recite "a biomedical superelastic Ti-base alloy" but do not require/recite specific shape memory effect/properties (not taught or expected by the prior art). Applicant has not clearly shown a nexus between the merits of the claimed invention and the evidence of secondary considerations (for MPEP 716.01b, MPEP 716.01-02 in general). Evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims. See In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) and MPEP §716.02(d) - § 716.02(e).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janelle Combs-Morillo whose telephone number is (571) 272-1240. The examiner can normally be reached on 8:30 am- 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JCM
March 13, 2007

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